DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

D1333 B

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

August 20, 1997

WARNING LETTER
CHI-41-97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Otto T. Nonnenmann
President & CEO
SoloPak Laboratories, Inc.,
1845 Tonne Road
Elk Grove Village, IL 60007-5125

Dear Mr. Nonnenmann:

A limited inspection of your firm was conducted from August 13-14, 1997, by Investigators Susan Bruederle and Nalini Patel. The inspection covered the production and distribution of Hydralazine Hydrochloride Injection, USP by your firm.

The inspection revealed that SoloPak has manufactured and distributed at least [redacted] lots of Hydralazine Hydrochloride Injection in 1997. These lots were all assigned an eighteen (18) month expiration date. However, the inspection determined that the stability studies your firm has conducted on this product shows that particles form after six (6) months storage in the inverted position.

The Investigators also documented that SoloPak's examination of Quality Control stability samples of Hydralazine Hydrochloride Injection, USP, lot #960570, revealed that [redacted] of [redacted] vials examined at the 6 month test station and [redacted] of [redacted] vials examined at the 9 and 12 month stations contained particles. This lot was manufactured in May 1996.

Hydralazine HCL lot #960570 is subject to the agreement reached between SoloPak and CDER on October 23, 1996, which was later memorialized in a letter dated October 28, 1996, from Rashmikant M. Patel, Ph.D., Director, Division of Chemistry, Office of Generic Drugs, CDER, to Donna Helms, Director, Regulatory Affairs. Lot #960570 was one of the 14 lots covered under the agreement. The agreement, in part, was that SoloPak would withdraw lots in which particulates are observed at more than one test station. The instant inspection revealed that [redacted]% of the vials examined contained particulates at two test stations. We also would like for you to advise this office of your plans concerning this lot. This lot is labeled with an expiration date of "11/97".

With regards to the status of the [redacted] lots of Hydralazine Hydrochloride Injection, USP, which SoloPak manufactured and distributed in 1997, the inspection revealed that an 18 month expiration date cannot be supported for this product based on the data obtained from the stability studies. We request that you advise this office of your plans regarding those lots of this product which have been distributed and are in the marketplace.

The [redacted] lots of Hydralazine Hydrochloride Injection, USP, manufactured by SoloPak during 1997, are not subject to the agreement reached between SoloPak and FDA/CDER in October 1996, and the criteria established by that agreement for 14 lots of pre 1997 production cannot be applied to these lots.

This letter, as well as the Inspectional Observations, Form FDA 483, issued and discussed at the conclusion of the inspection is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the CGMPs.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and provide the information we requested regarding those lots of Hydralazine Hydrochloride Injection, USP, which have been distributed and are in the market place.

Your reply should be sent to George F. Bailey, Compliance Officer.

Sincerely,

/s/

Raymond V. Mlecko
District Director

cc: Stanley Alekman, Ph.D.
Vice President/Quality
Regulatory and Scientific Affairs
SoloPak Laboratories
1845 Tonne Road
Elk Grove Village, IL 60007-5125

cc: Zena G. Kaufman
Director of Quality Assurance/Compliance
SoloPak Laboratories
1845 Tonne Road
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cc: Donna K. Helms
Director, Regulatory Affairs
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